PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P68878PC00	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/IB 03/06399	International filing date *(day/month/year)* 05.12.2003	Priority date *(day/month/year)* 05.12.2002
International Patent Classification (IPC) or both national classification and IPC A61B5/053		
Applicant UNIVERSITY OF ULSTER et al		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 9 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05.07.2004	07.03.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - Gitschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840	Authorized Officer Trachterna, M Telephone No. +49 30 25901-592

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/IB 03/06399

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

1-14 as originally filed

Claims, Numbers

1-29 received on 21.02.2005 with letter of 15.02.2005

Drawings, Sheets

1/5-5/5 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

see separate sheet

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-26
	No:	Claims	
Inventive step (IS)	Yes:	Claims	17,26
	No:	Claims	1-16,18-25
Industrial applicability (IA)	Yes:	Claims	1-26
	No:	Claims	

2. Citations and explanations

see separate sheet

Re Item I
Basis of the report

The amendments filed with the letter dated 15.02.2005 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:

- means for presenting at least one value representing a physical characteristic of at least one region of tissue.

The disclosure of the present application (see p. 13/l. 5-9) is limited to the presentation of area and ratio calculated on measured impedance values. Neither the claims nor the description (see in particular p. 7/l. 20-26) as originally filed support the above broadening of independent claims 1, 20.

Further the applicant has broadened the scope of protection by replacing the "tissue mapping" system or method by a "tissue measurement" system or method (see claims 1, 20).

These amendments introduce subject-matter which extends beyond the content of the application as filed. Consequently, the reasoned statement with regard to novelty, inventive step and industrial applicability has been established on the basis of claims 1-26 filed with the letter dated 01.12.2004.

Re Item V
Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1: LACKERMEIER A H ET AL: "IN VIVO AC IMPEDANCE SPECTROSCOPY OF HUMAN SKIN THEORY AND PROBLEMS IN MONITORING OF PASSIVE PERCUTANEOUS DRUG DELIVERY" ANNALS OF THE NEW YORK ACADEMY OF SCIENCES, NEW YORK ACADEMY OF SCIENCES, NEW YORK, NY, US, vol. 873, 20 April 1999, pages 197-213, XP008029774 ISSN:

0077-8923

D2: US 2002/082668 A1 (INGMAN DOV) 27 June 2002

D3: US-A-5 184 620 (CUDAHY MICHAEL J ET AL) 9 February 1993

1. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-16, 18-25 does not involve an inventive step in the sense of Article 33(3) PCT.

1.1 The document D3 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document): a tissue mapping system comprising (col. 6/l. 32-33):

- a two dimensional array of test electrodes (col. 5/l. 45-47, fig. 1(12))) for application to the surface of tissue under investigation; and
- circuit means (col. 6/l. 24-30, fig. 1(36)) for measuring an electrical characteristic of the tissue underlying each test electrode;

The subject-matter of claim 1 therefore differs from this known mapping system of D1 in that: a display device provides a visual map of the tissue based upon the measured electrical characteristics.

The problem to be solved by the present invention may therefore be regarded as how to provide a visual representation of the measured electrical characteristics.

However, the skilled person would regard it as a normal option to connect the mapping systemof D1 which is adapted to be connected to external diagnostic or monitoring devices (col. 6/l. 22-24) to a display device providing a visual map of the tissue based upon the measured electrical characteristics. Therefore, the solution proposed in claim 1 of the present application does not involve an inventive step (Article 33(3) PCT).

1.2 The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claim 18, which therefore is also considered not inventive.

1.3 Dependent claims 2-16, 19-25 do not contain any features which, in combination with

the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, see document D1, D3 and the corresponding passages cited in the search report.

2. The combination of the features of dependent claims 17, 26 is neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:

The subject-matter of claims 17, 26 is new (Article 33(2) PCT) (see 1.1 and 1.2 above).

The problem to be solved by the present invention may be regarded as how to monitor the progression of wound healing. In order to solve the problem the array of test electrodes is incorporated into a wound dressing. Since no indication nor even a hint has been found in the available prior art, which would have caused the skilled person to extend the known mapping system of D1 by the incorporation of the array of test electrodes into a wound dressing, the subject-matter of dependent claims 17, 26 is considered as involving an inventive step (Article 33(3) PCT).

3. The industrial applicability (Art. 33(4) PCT) is clearly given for the subject-matter of all apparatus claims. However, it is noted that no unified criteria exists as regards industrial applicability of diagnostic methods. If the method claims are maintained, this issue will therefore be the subject of further examination in a later regional/national phase.

Claims

1. A tissue measurement system comprising a two-dimensional array of test electrodes for application to the surface of tissue under investigation, circuit means for measuring an electrical characteristic of the tissue underlying each test electrode, and means for presenting at least one value representing a physical characteristic of at least one region of tissue based upon the measured electrical characteristics.

2. A system as claimed in claim 1, wherein the physical characteristic is area.

3. A system as claimed in claim 2, wherein the presenting means presents a plurality of values on a display device to provide a visual map representing the physical extent of the region of tissue.

4. A system as claimed in claim 1, 2 or 3, wherein the array of test electrodes is arranged on a flexible backing of insulating material.

5. A system as claimed in claim 4, wherein the array of electrodes is a rectangular array.

6. A system as claimed in claim 4 or 5, wherein each test electrode is covered with a conductive gel, the resistance between adjacent test electrodes being high relative to the resistance via the gel between each test electrode and the underlying tissue.

7. A system as claimed in claim 6, wherein the gel is hydrogel.

8. A system as claimed in any one of claims 4 to 7, wherein leads for the test electrodes are also disposed on the flexible backing of insulating material and covered with an insulating material.

9. A system as claimed in any preceding claim, wherein the two-dimensional array comprises at least 25 test electrodes.

10. A system as claimed in any preceding claim, wherein the electrical characteristic is the impedance of the tissue underlying each test electrode.

11. A system as claimed in any preceding claim, wherein the circuit means measures the electrical characteristic by applying an alternating electrical signal between the test electrode and at least one other electrode applied to the organic body of which the tissue forms a part.

12. A system as claimed in claim 11, wherein the circuit means measures the electrical characteristic by measuring the voltage between each test electrode and an adjacent reference electrode also applied to the tissue.

13. A system as claimed in claim 12, wherein the reference electrode is also disposed on the flexible backing of insulating material.

14. A system as claimed in claim 13, wherein a single reference electrode is common to a plurality of test electrodes.

15. A system as claimed in claim 13, wherein during measurement on a given test electrode an adjacent test electrode acts temporarily as its reference electrode.

16. A system as claimed in any one of claims 11 to 15, wherein the said at least one other electrode is also disposed on the flexible backing of insulating material.

17. A system as claimed in any one of claims 11 to 16, wherein for each test electrode a measurement is made at a plurality of different frequencies.

18. A system as claimed in any one of claims 11 to 17, wherein the or each measurement is made at a frequency of from 1 milliHz to 100 kHz, preferably from 1 Hz to 50 kHz.

19. A system as claimed in any preceding claim, wherein the array of test electrodes is incorporated into a wound dressing.

20. A method of measuring tissue comprising applying a two-dimensional array of test electrodes to the surface of tissue under investigation, measuring an electrical characteristic of the tissue underlying each test electrode, and presenting at least one value representing a physical characteristic of at

least one region of tissue based upon the measured electrical characteristics.

21. A method as claimed in claim 20, wherein the physical characteristic is area.

22. A method as claimed in claim 21, wherein a plurality of values are presented on a display device to provide a visual map representing the physical extent of the region of tissue.

22. A method as claimed in claim 20, 21 or 22, wherein the array of test electrodes is arranged on a flexible backing of insulating material.

23. A method as claimed in claim 22, wherein each test electrode is covered with a conductive gel, the resistance between adjacent test electrodes being high relative to the resistance via the gel between each test electrode and the underlying tissue.

24. A method as claimed in any one of claims 20 to 23, wherein the two-dimensional array comprises at least 25 test electrodes.

25. A method as claimed in any one of claims 20 to 24, wherein the electrical characteristic is the impedance of the tissue underlying each test electrode.

26. A method as claimed in any one of claims 20 to 25, wherein the electrical characteristic is measured by applying an alternating electrical signal between the test electrode and at least one other electrode

applied to the organic body of which the tissue forms a part.

27. A method as claimed in claim 26, wherein the electrical characteristic is measured by measuring the voltage between each test electrode and an adjacent reference electrode also applied to the tissue.

28. A method as claimed in claim 26 or 27, wherein for each test electrode a measurement is made at a plurality of different frequencies.

29. A method as claimed in any one of claims 20 to 28, wherein the array of test electrodes is incorporated into a wound dressing and applied to a wound.

Claims

1. A tissue mapping system comprising a two-dimensional array of test electrodes for application to the surface of tissue under investigation, circuit means for measuring an electrical characteristic of the tissue underlying each test electrode, and a display device providing a visual map of the tissue based upon the measured electrical characteristics.

2. A system as claimed in claim 1, wherein the array of test electrodes is arranged on a flexible backing of insulating material.

3. A system as claimed in claim 2, wherein the array of electrodes is a rectangular array.

4. A system as claimed in claim 2 or 3, wherein each test electrode is covered with a conductive gel, the resistance between adjacent test electrodes being high relative to the resistance via the gel between each test electrode and the underlying tissue.

5. A system as claimed in claim 4, wherein the gel is hydrogel.

6. A system as claimed in any one of claims 2 to 5, wherein leads for the test electrodes are also disposed on the flexible backing of insulating material and covered with an insulating material.

7. A system as claimed in any preceding claim, wherein the two-dimensional array comprises at least 25 test electrodes.

8. A system as claimed in any preceding claim, wherein the electrical characteristic is the impedance of the tissue underlying each test electrode.

9. A system as claimed in any preceding claim, wherein the circuit means measures the electrical characteristic by applying an alternating electrical signal between the test electrode and at least one other electrode applied to the organic body of which the tissue forms a part.

10. A system as claimed in claim 9, wherein the circuit means measures the electrical characteristic by measuring the voltage between each test electrode and an adjacent reference electrode also applied to the tissue.

11. A system as claimed in claim 10, wherein the reference electrode is also disposed on the flexible backing of insulating material.

12. A system as claimed in claim 11, wherein a single reference electrode is common to a plurality of test electrodes.

13. A system as claimed in claim 11, wherein during measurement on a given test electrode an adjacent test electrode acts temporarily as its reference electrode.

14. A system as claimed in any one of claims 9 to 13, wherein the said at least one other electrode is also disposed on the flexible backing of insulating material.

15. A system as claimed in any one of claims 9 to 14, wherein for each test electrode a measurement is made at a plurality of different frequencies.

16. A system as claimed in any one of claims 9 to 15, wherein the or each measurement is made at a frequency of from 1 milliHz to 100 kHz, preferably from 1 Hz to 50 kHz.

17. A system as claimed in any preceding claim, wherein the array of test electrodes is incorporated into a wound dressing.

18. A method of mapping tissue comprising applying a two-dimensional array of test electrodes to the surface of tissue under investigation, measuring an electrical characteristic of the tissue underlying each test electrode, and displaying a visual map of the tissue based upon the measured electrical characteristics.

19. A method as claimed in claim 18, wherein the array of test electrodes is arranged on a flexible backing of insulating material.

20. A method as claimed in claim 19, wherein each test electrode is covered with a conductive gel, the resistance between adjacent test electrodes being

high relative to the resistance via the gel between each test electrode and the underlying tissue.

21. A method as claimed in any one of claims 18 to 20, wherein the two-dimensional array comprises at least 25 test electrodes.

22. A method as claimed in any one of claims 18 to 21, wherein the electrical characteristic is the impedance of the tissue underlying each test electrode.

23. A method as claimed in any one of claims 18 to 22, wherein the electrical characteristic is measured by applying an alternating electrical signal between the test electrode and at least one other electrode applied to the organic body of which the tissue forms a part.

24. A method as claimed in claim 23, wherein the electrical characteristic is measured by measuring the voltage between each test electrode and an adjacent reference electrode also applied to the tissue.

25. A method as claimed in claim 23 or 24, wherein for each test electrode a measurement is made at a plurality of different frequencies.

26. A method as claimed in any one of claims 18 to 25, wherein the array of test electrodes is incorporated into a wound dressing and applied to a wound.

Box No. VIII (iv) **DECLARATION: INVENTORSHIP (only for the purposes of the designation of the United States of America)**

The declaration must conform to the following standardized wording provided for in Section 214; see Notes to Boxes Nos. VIII, VIII (i) to (v) (in general) and the specific Notes to Box No. VIII (iv). If this Box is not used, this sheet should not be included in the request.

Declaration of inventorship (Rules 4.17(iv) and 51bis.1(a)(iv))
for the purposes of the designation of the United States of America:

I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought.

This declaration is directed to the international application of which it forms a part (if filing declaration with application).

This declaration is directed to international application No. PCT/..... (if furnishing declaration pursuant to Rule 26*ter*).

I hereby declare that my residence, mailing address, and citizenship are as stated next to my name.

I hereby state that I have reviewed and understand the contents of the above-identified international application, including the claims of said application. I have identified in the request of said application, in compliance with PCT Rule 4.10, any claim to foreign priority, and I have identified below, under the heading "Prior Applications," by application number, country or Member of the World Trade Organization, day, month and year of filing, any application for a patent or inventor's certificate filed in a country other than the United States of America, including any PCT international application designating at least one country other than the United States of America, having a filing date before that of the application on which foreign priority is claimed.

Prior Applications: .....

I hereby acknowledge the duty to disclose information that is known by me to be material to patentability as defined by 37 C.F.R. § 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the PCT international filing date of the continuation-in-part application.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

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Inventor's Signature: .....
(if not contained in the request, or if declaration is corrected or added under Rule 26*ter* after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: 20/02/04
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26*ter* after the filing of the international application)

Name: .....

Residence: .....
(city and either US state, if applicable, or country)

Mailing Address: .....

Citizenship: .....

Inventor's Signature: .....
(if not contained in the request, or if declaration is corrected or added under Rule 26*ter* after the filing of the international application. The signature must be that of the inventor, not that of the agent)

Date: .....
(of signature which is not contained in the request, or of the declaration that is corrected or added under Rule 26*ter* after the filing of the international application)

☐ This declaration is continued on the following sheet, "Continuation of Box No. VIII (iv)".